REMARKS

1. Introduction

In the Office Action mailed December 1, 2006, the Examiner made the restriction requirement final and withdrew claims 14-18 and 20 from further consideration as being drawn to a non-elected invention. Claims 9-13 were previously canceled. Thus, claims 1-8 and 19 are currently under examination.

The Examiner rejected one or more claims in the present application (the Examiner did not specify which claims) based on nonstatutory obviousness-type double patenting over claim 1 of Jolley et al., U.S. Patent No. 5,976,820 ("the '820 patent").

The Examiner rejected claims 1-8 and 19 under 35 U.S.C. § 112, ¶ 2 as being allegedly indefinite because of the "detectable change" language in claim 1.

The Examiner rejected claims 1, 3-8, and 19 under 35 U.S.C. § 102(a) as being allegedly anticipated by Gast et al., *Avian Diseases*, 46:137-142, Jan-Mar 2002 ("Gast").

The Examiner rejected claims 1-4, 6-8, and 19 under 35 U.S.C. § 102(b) as being allegedly anticipated by Nasir et al., "Detection of *Salmonella enteriditis* Infections in Chickens and Egg Yolks Using Fluorescence Polarization," *Proceedings of the One Hundred and Fourth Meeting of the United States Animal Health Association*, October 20-27, 2000 ("Nasir").

The Examiner rejected claims 1-8 and 19 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Nasir in view of Gast.

In addition, the Examiner remarked on the use of trademarks in the specification, stating that trademarks should be capitalized and be accompanied by the generic terminology.

For the reasons set forth below, Applicants respectfully request reconsideration and allowance of the claims.

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2. Trademarks in the Specification

The Examiner has requested appropriate correction in the specification so that trademarks appear capitalized and are accompanied by the generic terminology. In response, Applicants have amended the specification to change "Sentry-FP™" to "SENTRY-FP™ fluorescence polarization analyzer."

3. Response to Double Patenting Rejection

The Examiner has rejected one or more claims in the present application (the Examiner did not specify which claims) based on nonstatutory obviousness-type double patenting over claim 1 of the '820 patent. Specifically, the Examiner has argued that the two sets of claims overlap in scope, in that claim 1 of the '820 patent allegedly encompasses a method of detecting a genus of bacterial antigens and the instant claims encompass a method of detecting a species of bacterial antigens (*Salmonella*). *See* Office Action, p. 5.

In response, Applicants respectfully submit that the Examiner's double-patenting rejection is based on a misreading claim 1 of the '820 patent. In particular, the Examiner's double-patenting rejection is premised on the Examiner's understanding that "[t]he method of U.S. Patent No. 5,976,820 recites detecting bacterial antigen." *See* Office Action, p. 5. In fact, claim 1 of the '820 patent recites a "method for detecting in a homogenous assay ***antibodies*** to a bacterial O-antigen present in a fluid." Thus, the Examiner has apparently confused the method for detecting ***antibodies*** to a bacterial antigen, which is the subject of claim 1 of the '820 patent, with the method for detecting the antigen itself, which is the subject of the claims of the present application. Applicants further submit that the difference between detecting antibodies and detecting antigens is substantial. For example, antigens may be detected in samples, such as

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food products (e.g., as in claim 4) or animal feces (e.g., as in claim 5), for which antibody detection may not feasible.

Because claim 1 of the '820 patent is directed to a method for detecting ***antibodies***, whereas the claims in the present application are directed to a method for detecting ***antigens***, Applicants submit that these claims do not overlap in scope. Accordingly, Applicants respectfully submit that the double patenting rejection is improper and should be withdrawn.

4. Response to § 112 Rejections

The Examiner has rejected claims 1-8 and 19 under 35 U.S.C. § 112, ¶ 2 as being allegedly indefinite because of the "detectable change" language in claim 1.

The test for definiteness under 35 U.S.C. § 112, ¶ 2 is whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. *See* MPEP 2173.02. Applicants submit that the claims clearly meet that test.

Claim 1 recites "said tracer being able to bind to said anti-*Salmonella* antibody to produce a detectable change in fluorescence polarization." One of ordinary skill in the art would understand that this claim language refers to the principle that binding results in a larger molecule, which, in turn tends to have a higher fluorescence polarization. *See* page 2 of the specification. Thus, binding can often be detected by detecting a change in fluorescence polarization.

Moreover, one skilled in the art would understand that the studies reported in Table 1 of the specification (*see* pages 9 and 10) were conducted in order to determine which tracers would bind with which antibodies to produce a detectable change in fluorescence polarization. The specification states: "It was found that AB2 reacted only with SE tracers and AB3 reacted only

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with ST tracers, as indicated by the delta mP columns in Table 1." *See* page 9, lines 16-17. Consistent with this statement, Table 1 shows that significant changes in fluorescence polarization (the "delta mP" column) were observed when the AB2 antibody was combined with the SE tracers (a 82 mP change for SE.1 and an 85 mP change for SE.5) and when the AB3 antibody was combined with the ST tracers (a 42 mP change for ST.01 and a 51 mP change for ST.1). These results show an increase in fluorescence polarization consistent with tracer binding to antibody. However, when the AB2 antibody was combined with the ST tracers and when the AB3 antibody was combined with the SE tracers, zero or slightly negative delta mP values were observed. These zero and negative delta mP values are not indicative of binding between tracer and antibody.

Applicants submit that, given these examples in the specification, the claim language "said tracer being able to bind to said anti-*Salmonella* antibody to produce a detectable change in fluorescence polarization" read in light of the specification would be readily understandable to one of ordinary skill in the art. Therefore, the rejection under 35 U.S.C. § 112, ¶ 2 should be withdrawn.

5. Response to § 102 Rejections Over Gast

Applicants respectfully submit that the Examiner's § 102 rejection based on Gast is based on a misreading of Gast. The Examiner has argued that "Gast et al teach a method of detecting *Salmonella* antigens in fecal samples and serum samples using fluorescence polarization and enzyme immunoassay (see the Abstract)." As an initial matter, Applicants understand the Examiner to be referring to the "Summary" section, because Gast does not actually include an "Abstract" section.

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More importantly, Applicants note that Gast's Summary actually refers to the detection of ***antibodies***, not the detection of ***antigens***:

> The present study evaluated the detection of ***antibodies*** in the sera of experimentally infected chickens by a fluorescence polarization assay with a tracer prepared from the O-polysaccharide of *S. enteriditis* and an enzyme-linked immunosorbent assay (ELSIA) with an *S. enteriditis* flagellin antigen.

See Gast, p. 137, second sentence of Summary (emphasis added). Thus, Applicants respectfully submit that the Examiner has misread Gast's Summary as referring to the detection of ***antigens*** using fluorescence polarization, when Gast's Summary actually refers to the detection of ***antibodies*** using fluorescence polarization.

Applicants respectfully submit that the Examiner has also misread Gast's Summary as referring to fluorescence polarization assays of fecal samples. In fact, Gast's Summary does not mention to fecal samples at all. Gast does refer to fecal samples in the "Materials and Methods" section on p. 138. However, that section makes clear that *Salmonella* was detected in the fecal samples by ***culturing*** the fecal samples, not by fluorescence polarization.

In Gast, fluorescence polarization was only used to detect ***antibodies*** in serum samples. *See* Gast, p. 137 ("Summary") and p. 139 ("Detection of specific antibodies by FP"). In contrast, claim 1 is directed to a method of detecting *Salmonella* ***antigens*** in a sample by fluorescence polarization. For this reason alone, Gast does fails to disclose each and every element of claim 1.

In addition, claim 1 recites "combining said sample with a tracer ***and an anti-Salmonella antibody*** to form an assay mixture." Applicants submit that Gast does not disclose combining the sample with an anti-*Salmonella* antibody to form an assay mixture for fluorescence polarization. Indeed, because Gast teaches using fluorescence polarization to detect anti-*Salmonella* antibodies

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that are already present in the sample, there would be no reason to combine the sample with an anti-*Salmonella* antibody.

Accordingly, Applicants submit that the § 102 rejections based on Gast are improper and should be withdrawn because Gast fails to disclose each and every element of claim 1. Applicants further submit that claims 2-8 and 19 are patentable over Gast for at least the same reasons as claim 1, from which these claims depend.

6. Response to § 102 Rejections Over Nasir

Applicants respectfully submit that, like Gast, Nasir also fails to disclose each and every element of claim 1.

Claim 1 recites a "method for detecting *Salmonella* ***antigens*** in a sample." In contrast, Nasir discloses a fluorescence polarization assay (FPA) for the detection of ***antibodies*** to *Salmonella enteriditis*. *See* Nasir, Abstract, first sentence. The samples for which FPA was used to detect antibodies in Nasir included serum samples (Table 1 in Nasir) and egg yolk samples (Table 2 in Nasir). Because Nasir discloses the use of FPA for the detection of ***antibodies***, rather than ***antigens***, Nasir fails to disclose each and every element of claim 1. For this reason alone, the § 102 rejections based on Nasir are improper and should be withdrawn.

In addition, claim 1 recites "combining said sample with a tracer ***and an anti-Salmonella antibody*** to form an assay mixture." The Examiner has alleged that Nasir teaches "the method steps of combining the tracer with the anti-*Salmonella* antibody," citing to the Abstract. However, claim 1 actually recites combining the ***sample*** with a tracer and an anti-*Salmonella* antibody. This step is not taught in Nasir for the simple reason that the sample already contains the anti-*Salmonella* antibodies that are to be detected. Thus, there would be no reason to combine the

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sample in Nasir with an anti-*Salmonella* antibody. Not surprisingly, Nasir's Abstract describes combining the sample with a tracer, not with an anti-*Salmonella* antibody:

> Sample (10 or 20 ml) was diluted into 1 ml of buffer and a blank serum reading was taken. 10 ml of an appropriately diluted tracer added, mixed and its FP measured after 2 minutes. A positive sample was indicated by a reading of 10 mP higher than that of the tracer in buffer.

See Nasir, Abstract. Because Nasir does not disclose combining the sample with an anti-Salmonella antibody, Nasir fails to disclose each and every element of claim 1. For this reason also, the § 102 rejections based on Nasir are improper and should be withdrawn.

Accordingly, Applicants submit that the § 102 rejections based on Nasir are improper and should be withdrawn because Nasir fails to disclose each and every element of claim 1. Applicants further submit that claims 2-8 and 19 are patentable over Nasir for at least the same reasons as claim 1, from which these claims depend.

7. Response to § 103 Rejections

The Examiner has rejected claims 1-8 and 19 under 35 U.S.C. § 103 as being unpatentable over Nasir in view of Gast. However, as noted above, Nasir and Gast both fail to disclose a "method for detecting *Salmonella* antigens in a sample," as recited in claim 1. Further, Nasir and Gast both fail to disclose "combining said sample with a tracer and an anti-*Salmonella* antibody to form an assay mixture," as recited in claim 1. Because Nasir and Gast both fail to disclose these elements of claim 1, the combination of Nasir and Gast also fails to disclose these elements.

Accordingly, Applicants submit that the § 103 rejections based on Nasir in view of Gast are improper and should be withdrawn because the Nasir/Gast combination fails to disclose each and

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every element of claim 1. Applicants further submit that claims 2-8 and 19 are patentable over Nasir and Gast for at least the same reasons as claim 1, from which these claims depend.

8. Conclusion

Applicants submit that the present application is in condition for allowance, and notice to that effect is hereby requested. Should the Examiner feel that further dialog would advance the subject application to issuance, the Examiner is invited to telephone the undersigned at any time at (312) 913-0001.

Respectfully submitted,

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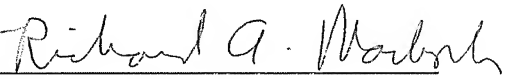
By: 

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